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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,129	06/24/2003	David J. Schuessler	33915-03420	9875
27171	7590	06/24/2005	EXAMINER	
MILBANK, TWEED, HADLEY & MCCLOY LLP 1 CHASE MANHATTAN PLAZA NEW YORK, NY 10005-1413				RAYFORD, SANDRA M
ART UNIT		PAPER NUMBER		
		1772		

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/603,129	SCHUESSLER, DAVID J.
	Examiner Sandra M. Nolan-Rayford	Art Unit 1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 March 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 23-44 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 23-38 and 44 is/are rejected.  
 7) Claim(s) 39-43 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Page 3 of decln; 2 pages from 10/603904.

## **DETAILED ACTION**

### ***Claims***

1. Claims 23-44 are pending.

### ***Priority***

2. It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/908,414, filed 18 July 2001.

A reference to the prior application has been inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76).

For benefit claims under 35 U.S.C. 120, the current status of all nonprovisional parent applications referenced should be included.

Suggested amendment:

On pages 1, in the paragraph added via the 20 August 2004 amendment, immediately after "2001", the phrase -- now U.S. 6,602,452 -- should be added.

### ***Comment re: Declaration***

3. The examiner notes that applicant revised his residence address when he signed the 24 June 2003 declaration (eDAN date) for this case. See *the enclosed revised declaration page*.

It is suggested that applicant submit a supplemental declaration, including his current address.

### ***Summary of Base Claim***

4. The sole base claim, claim 23, as shown in the 03 August 2004 amendment, can be summarized as follows:

Claim 23 covers a medical article comprising:

a multi-axis rotationally molded shell defining an exterior cavity, which shell is formed from at least one layer of a polymer material.

***Allowable Subject Matter***

5. Claims 39-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. The applicable prior art fails to teach or suggest rotationally molded medical articles made from the polymers or solvent-based resins recited in these claims.

***Rejections Withdrawn***

7. All rejections made in the 30 June 2004 office action have been withdrawn for the following reasons:

The 35 USC 102 rejection of claim 23 as anticipated by Cumer et al (US-5,665,069) has been overcome by the amendments and arguments presented in the 30 March 2005 response ("the last response").

The 35 USC 102 rejection of claims 23, 35 and 42 as anticipated by Shah (US-6,291,543) has been overcome by the Rule 131 declaration of inventor David Schuessler, dated 28 March 2005 and submitted with the last response.

The 35 USC 103 rejection of claims 23, 35 and 42 as anticipated by O'Hara (US-6,231,547) has been overcome by the Schuessler declaration.

The 35 USC 103 rejection of claims 23 and 40 as unpatentable over O'Hara in view of Yoshino (US 5,519,082) has been overcome by the Schuessler declaration.

The 35 USC 103 rejection of claims 23, 35 and 41 as unpatentable over O'Hara in view of Revis (US 5,091,445) has been overcome by the Schuessler declaration.

The provisional obviousness-type double patenting rejection of claims 39-44 over claims 23-38 of SN.10/603,404 has been overcome by the fact that claims 23-38 of the '404 application were cancelled on 24 June 2003, not "June 24, 2004" [emphasis added], in that case.

A copy of the transmittal letter and the first page of the 24 June 2003 amendment from the eDAN file for SN.10/603904 are enclosed.

The statutory double patenting rejection of claims 23-38 over claims 23-38 of the '904 has been overcome by the fact that claims 23-38 of the '404 application were cancelled on 24 June 2003.

### ***New Rejections***

#### **Claim Rejections - 35 USC § 102**

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claim 23 is rejected under 35 U.S.C. 102(e) as being anticipated by Nishikawa et al (US 6,225,424).

Nishikawa teaches polyethylene containers (col. 1, line 9) for medical products (col. 1, line 12) made by rotationally molding (col. 7, line 35).

Containers are well known in the art to be multiaxial shells with interior cavities.

Claim 23 is rejected under 35 U.S.C. 102(e) as being anticipated by Kozimor et al (US 6,231,936).

Kozimor teaches hypodermic syringes having barrels (col. 8, lines 46-47) and test tubes (col. 8, line 54) made of polypropylene (col. 2, line 35) sing rotational molding (col. 16, line 43).

Syringe barrels and test tubes are well known in the art to be multiaxial shells with interior cavities.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 24-38 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishikawa.

Nishikawa is discussed above.

It fails to teach the shell features, thickness, filler, lining features of claims 24-34, the forms recited in claims 35-38, or the gaseous byproducts of claim 44.

The provision of various textures, fillers and the like in the articles of Nishikawa is deemed a matter of design choice.

The use of the Nishikawa compositons/processes to make medical articles having various forms is deemed a matter of intended use and does not render the claims patentable over Nishikawa.

In the absence of convincing objective evidence to the contrary, the curing and production of gaseous byproducts during curing of the Nishikawa compositons are deemed conventional.

13. Claims 24-38 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozimor.

Kozimor is discussed above.

It fails to teach the shell features, thickness, filler, lining features of claims 24-34 and the forms recited in claims 35-38.

The provision of various textures, fillers and the like in the articles of Nishikawa is deemed a matter of design choice.

The use of the Kozimor compositons/processes to make medical articles having various forms is deemed a matter of intended use and does not render the claims patentable over Nishikawa.

In the absence of convincing objective evidence to the contrary, the curing and production of gaseous byproducts during curing of the Kozimor compositons are deemed conventional.

***Conclusion***

Any inquiry concerning this communication should be addressed to Sandra M. Nolan-Rayford, at telephone number 571/272-1495. She can be reached Monday through Thursday, from 6:30 am to 4:00 pm, ET.

If attempts to reach the examiner are unsuccessful, contact her supervisor, Harold Pyon, at 571/272-1498.

The fax number for patent application documents is 703/872-9306.

*S. M. Nolan-Rayford 6-16-05*  
S. M. Nolan-Rayford  
Primary Examiner  
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